

UNITED STATES DISTRICT COURT  
District of New Jersey

CHAMBERS OF  
JOSE L. LINARES  
JUDGE

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NOT FOR PUBLICATION

**LETTER OPINION**  
**ORIGINAL TO BE FILED WITH THE CLERK OF THE COURT**

February 5, 2007

**Re: Altana v. Sun, No. 04-2355**  
**Motion for Reconsideration filed in No. 05-3920**

Dear Parties:

Currently before the Court is a motion for reconsideration pursuant to L. Civ. R. 7.1(i) filed by Defendants Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Advanced Research Centre, Ltd. (collectively, "Defendants"). Defendants ask the Court to reconsider its June 13, 2006 opinion and order dismissing Defendants' third and fourth counterclaims against Plaintiffs, Altana Pharma AG and Wyeth (collectively, "Plaintiffs") without prejudice for lack of subject matter jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1). For the following reasons, the Court denies Defendants' motion.

**I. Factual and Procedural History**

The parties are familiar with the factual history of this case; therefore, the Court will not discuss such in depth in this letter opinion. In sum, Plaintiffs sued Defendants for infringement of Plaintiffs' United States Patent No. 4,758,579 (the " '579 patent"). The '579 patent is one of two patents which make up the drug Protonix IV, which, in an injectable form, is used to treat extreme forms of heart burn.<sup>1</sup> The '579 patent identifies the compound for Protonix IV—the active ingredient is pantoprazole sodium. The second patent which comprises Protonix IV is United States Patent No. 6,780,881 (the " '881 patent"). The '881 patent covers the process for production of Protonix IV. Plaintiffs did not sue to enforce the '881 patent.

Defendants were sued because they filed an Abbreviated New Drug Application ("ANDA") in an effort to market a generic version of Protonix IV. In connection with the ANDA, Defendants filed a Paragraph IV Certification stating that their generic version of the drug does not infringe existing patents or that any such patents are invalid. Defendants answered Plaintiffs' complaint on the '579 patent and counterclaimed for a declaratory judgment that Plaintiffs' '881 patent was invalid and that Defendants did not infringe the '881 patent.

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<sup>1</sup> Protonix, as opposed to Protonix IV, is the tablet form of the drug. The '579 patent is common to both Protonix and Protonix IV.

In its June 13, 2006 opinion and order, the Court held that, after considering the totality of the circumstances, it lacked subject matter jurisdiction over Defendants' counterclaims because there was no explicit threat or other action by Plaintiffs which created an objectively reasonable apprehension that Defendants would face an infringement lawsuit on the '881 patent. See, e.g., BP Chem. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed. Cir. 1993) (citing Jervis B. Webb Co. v. Southern Sys., Inc., 742 F.2d 1388, 1398-99 (Fed. Cir. 1984).

In particular, the Court found that (1) Plaintiffs have never litigated on the '881 patent, only the '579 patent; (2) Plaintiffs could have sued on the '881 patent concurrently with the instant lawsuit on the '579 patent but chose not to do so; (3) Plaintiffs' litigation history in general did not evidence an intent to sue on the '881 patent; (4) Plaintiffs' refusal to assure Defendants that they would not sue to enforce the '881 patent did not create a reasonable apprehension of suit; and (5) the statement by Wyeth's CFO that they will defend their patents is insufficient to create a reasonable apprehension of suit on the '881 patent.

Defendants now claim that the Court should reconsider its decision because such was based on the following erroneous factual findings: (1) Teva, another pharmaceutical company, was the first to file an ANDA as to the '881 patent, thus requiring Defendants to await a 180 day exclusivity period before launching their generic version of Protonix IV; and (2) Plaintiffs could have, but chose not to, sued to enforce the '881 patent against Teva and Defendants in the earlier litigations involving their ANDA's for Protonix, the tablet form of the drug.

## **II. Standard of Review**

Local Civil Rule 7.1(i) states that a motion for reconsideration "setting forth concisely the matter or controlling decisions which the party believes the Judge or Magistrate Judge has overlooked" may be filed within ten business days after entry of an order. Reconsideration, however, is an extraordinary remedy and should be granted "very sparingly." See L. Civ. R. 7.1(i) cmt. 6(d); see also Fellenz v. Lombard Investment Corp., Nos. 04-3993, 04-5768, 04-3992, 04-6105, 2005 WL 3104145, at \*1 (D.N.J. Oct. 18, 2005) (citing Maldonado v. Lucca, 636 F. Supp. 621, 630 (D.N.J. 1986)).

There are three grounds for granting a motion for reconsideration: (1) an intervening change in controlling law has occurred; (2) evidence not previously available has become available; or (3) it is necessary to correct a clear error of law or prevent manifest injustice. See, e.g., Carmichael v. Everson, No. 03-4787, 2004 WL 1587894, at \*1 (D.N.J. May 21, 2004); Brackett v. Ashcroft, No. Civ. 03-3988, 2003 WL 22303078, at \*2 (D.N.J. Oct. 7, 2003). The instant motion for reconsideration involves only the third ground for reconsideration, namely, the necessity to correct a clear error of law or prevent manifest injustice. This generally means that the Court overlooked some dispositive factual or legal matter that was presented to it. See L. Civ. R. 7.1(i); see also Fellenz, 2005 WL 3104145, at \*1; Carmichael, 2004 WL 1587894, at \*1.

## **III. Legal Discussion**

The Court denies Defendants' motion for reconsideration because neither of the two purportedly inaccurate factual determinations were dispositive of the Court's June 13, 2006

finding that it lacked subject matter jurisdiction over Defendants' counterclaims on the '881 patent.

First, the Court's purportedly inaccurate finding that Teva, and not Defendants, had a 180 day exclusivity period to market its generic version of the drug, formed the premise for an *alternative* ground for the Court's disposition. The Court merely mentioned that such would *also* show that Defendants were not under an *immediate* threat of suit on the '881 patent. Even if, as it is now alleged, Defendants, and not Teva, are entitled to the statutory exclusivity period on the injectable form of the drug, such does not change the fact that the totality of the circumstances analysis, as more fully discussed below, weighs in favor of dismissing Defendants' counterclaims for lack of subject matter jurisdiction due to the absence of a reasonable apprehension of suit.

Furthermore, as Plaintiffs point out and Defendants do not challenge, even if Defendants were entitled to the statutory exclusivity period as to Protonix IV, other facts exist which illustrate the lack of an immediate threat of suit by Plaintiffs against Defendants on the 881 patent. Defendants purportedly have not obtained tentative approval from the FDA to market their Protonix IV product. Even if they receive such approval, Defendants are barred from marketing their drug by the '579 patent (which expires in 2010) and the thirty-month stay tied to the '579 patent pursuant to the Hatch-Waxman Act (which, according to Plaintiffs, does not expire until December 30, 2007).

In addition, the Court's purported failure to discuss whether Plaintiffs had standing to enforce the '881 patent in earlier litigations involving the tablet form of the drug does not alter the disposition of this matter. Although such may detract from the Court's finding that "Plaintiffs have never litigated on the '881 patent," and would factor into an analysis of Plaintiffs' "previously exhibited litigation tendencies," the totality of the circumstances still weighs in favor of dismissal of Defendants' counterclaims.

The Court considered many factors, as it is required to do, in holding that it lacked subject matter jurisdiction over Defendants' counterclaims on the '881 patent. It is undisputed that Plaintiffs in the instant lawsuit only sued to enforce the '579 patent, not the '881 patent. The Court explicitly stated that this fact was *particularly significant* in its June 13, 2006 opinion. It is also undisputed that Plaintiffs' litigation history shows that it has not litigated every patent on the Protonix drug. In particular, it is undisputed that Plaintiffs have consistently asserted only the '579 patent against multiple Protonix ANDA filings. Furthermore, Defendants point to no threat or any action by Plaintiffs, other than those already rejected by the Court, to evidence a reasonable apprehension of suit on the '881 patent.

The Court rejects Defendants' argument that the Court should now give particular weight to the fact that Plaintiff covenanted not to sue as to the formulation patent for the tablet version of the drug, U.S. Patent No. 5,997,903 (the "'903 patent"), while they did not so covenant with respect to the '881 patent, which is the formulation patent for the injectable version of the drug. The Court considered this argument in its June 13, 2006 opinion and rejected it. See, e.g., Carmichael, 2004 WL 1587894, at \*1 (stating that it is improper to ask the court to reconsider arguments previously considered and rejected by the court). In any event, this fact does not outweigh the factors listed above which evidence a lack of an actual controversy.

**IV. Conclusion**

Therefore, Defendants' motion for reconsideration is denied. An appropriate order accompanies this letter opinion.

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/s/ Jose L. Linares

UNITED STATES DISTRICT JUDGE